PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Sean McFerran	Confirmation No.:	7830
Serial No.:	10/667,056	Examiner:	Phillip A. Gray
Filing Date:	September 22, 2003	Group Art Unit:	3767
Docket No.:	1001.1708101	Customer No.:	11050
For:	MICROCATHETER WITH SLEEVED GUIDEWIRE PORT		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 9th day of May 2011.

By Kathleen L Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on and of the Notice of Panel Decision from Pre-Appeal Review dated.

Applicant hereby authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

Please consider this a PETITION FOR ONE-MONTH EXTENSION OF TIME to enter these papers. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One Scimed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Sean McFerran, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014533, Frame 0283. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1 – 12 and 14 have been canceled without prejudice by prior Amendment and claims 13 and 15 - 28 remain pending in the application.

Claims 13, 15-17, and 21-28 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Pfenninger (U.S. Patent No. 5,306,247) in view of Allman et al. (U.S. Patent No. 6,346,093).

Claims 18 – 20 have been indicated as allowable.

Appellant hereby appeals the final rejection of pending claims 13, 15 – 17, and 21 - 28.

IV. STATUS OF AMENDMENTS

A Notice of Appeal and Pre-Appeal Brief Request for Review were filed on January 13, 2011. A Notice of Panel Decision from Pre-Appeal Brief Review was mailed on March 10, 2011 indicating to proceed to the Board of Patent Appeals and Interferences and resetting the time period for filing an appeal brief to one month from the mailing of the Notice of Panel Decision from Pre-Appeal Brief Review.

As noted above, pending claims 13, 15 – 17, and 21 – 28 are being appealed.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

In accordance with one example embodiment, a catheter *(see, for example, Specification page 5, lines 3 – 13; page 12, lines 1 -5; reference numeral 10 shown in Figure 1; reference numeral 75 shown in Figure 8)* including an elongate shaft *(see, for example, Specification page 5, lines 14 – 16; page 5, line 21 – page 6 line 6; page 8, line 3 and lines 20 – 21; reference numeral 12 shown in Figures 1 and 2; reference numeral 32 shown in Figure 3; reference numeral 42 shown in Figures 4, 5, and 6)* defining a lumen therethrough *(see, for example, Specification page 5, line 22; page 6, lines 10 – 12; reference numeral 30 shown in Figures 2, 3, 5, 7, and 8)* and having a guidewire port *(see, for example, Specification page 8, lines 3 – 19; reference numeral 44 shown in Figures 4, 5, 6, 7, and 8).*

Turning specifically to the claims, where independent claim 13 recites a single lumen microcatheter, *(see, for example, Specification page 5, lines 3 – 13; page 12, lines 1 -5; reference numeral 10 shown in Figure 1; reference numeral 75 shown in Figure 8)*comprising an elongate shaft *(see, for example, Specification page 5, lines 14 – 16; page 5, line 21 – page 6 line 6; page 8, line 3 and lines 20 – 21; reference numeral 12 shown in Figures 1 and 2; reference numeral 32 shown in Figure 3; reference numeral 42 shown in Figures 4, 5, and 6)* having a distal end *(see, for example, Specification page 5, lines 14 – 15; reference numeral 16 shown in Figure 1)*and a proximal end *(see, for example, Specification page 5, lines 14 – 15; reference numeral 14 shown in Figure 1)*, the elongate shaft having an outer surface and an inner surface, the inner surface defining a single lumen extending from the proximal end to the distal end of the elongate shaft and fluidly connecting the proximal end to an opening at the distal end of the elongate *shaft (see, for example, Specification page 5, line 22 – page 6, line 3; page 6, lines 10 – 12; reference numeral 30 shown in Figures 2, 3, 5, 7, and 8)*, an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft *(see, for example, Specification page 8, lines 3 – 19; reference numeral 44 shown in Figures 4, 5, 6, 7, and 8)*, and a polymer sheath disposed over the elongate guidewire port *(see, for example, Specification page 8, line 20 – page 9, line 16; reference numeral 50 shown in Figures 6, 7, and 8)*, the polymer sheath having an inner surface *(see, for example, Specification page 10, lines 10*

[1] The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting.

– 11; reference numeral 62 shown in Figure 7) and an outer surface *(see, for example, Specification page 10, lines 10 – 11; reference numeral 60 shown in Figure 7)*, the polymer sheath having a length measured from a proximal end of the polymer sheath to a distal end of the polymer sheath *(see, for example, Specification page 9, lines 6 – 9)*, the polymer sheath including a passage *(see, for example, Specification page 9, line 14 – page 10, line 4; reference numeral 56 shown in Figures 6 and 7)*comprising an angled slit *(see, for example, Specification page 10, line 3 – page 11, line 4; reference numeral 58 shown in Figures 6 and 8)* extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath *(see, for example, Specification page 10, lines 15 – 22; reference numerals D3 and D4 shown in Figure 7)*, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit having a length measured parallel to the length of the polymer sheath and parallel to the longitudinal axis of the elongate shaft, the length of the slit being less than the length of the polymer sheath such that the slit extends along only a portion of the length of the polymer sheath *(see, for example, Specification page 10, lines 4 – 9)*, the passage in communication with the elongate guidewire port *(see, for example, Specification page 9, lines 14 -16)*, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage; and wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft *(see, for example, Specification page 9, line 16 – page 10, line 2)*.

Dependent claim 15 recites the single lumen microcatheter of claim 13 wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath *(see, for example, Specification page 10, lines 15 – 19)*.

Dependent claim 16 recites the single lumen microcatheter of claim 13 wherein the angled slit extends from the outer surface of the polymer sheath to the inner surface of the polymer sheath *(see, for example, Specification page 10, lines 10 – 11)*.

Dependent claim 17 recites the single lumen microcatheter of claim 13 wherein the angled slit is configured to accept both a guidewire and a sheath wherein the sheath is configured to accept the guidewire therein *(see, for example, Specification page 9, lines 16 – 19; page 12, lines 16 – 19; reference numerals 66 and 72 shown in Figure 8)*.

Dependent claim 21 recites the single lumen microcatheter of claim 13 wherein the guidewire port has a length and a width, wherein the length is at least three times greater than the width *(see, for example, Specification page 8, lines 3 – 9; reference numerals D1 and D2 shown in Figure 4)*.

Dependent claim 22 recites the single lumen microcatheter of claim 21 wherein the length is at least six times greater than the width *(see, for example, Specification page 8, lines 3 – 9; reference numerals D1 and D2 shown in Figure 4)*.

Dependent claim 23 recites the single lumen microcatheter of claim 21 wherein the guidewire port has a first wall and a second wall, wherein the first wall and the second wall extend parallel to the longitudinal axis of the elongate shaft and wherein the guidewire port length also extends parallel to the longitudinal axis of the elongate shaft *(see, for example, Specification page 8, lines 13 – 19; reference numerals 44 and 48 shown in Figure 5)*.

Dependent claim 24 recites the single lumen microcatheter of claim 13 wherein the slit has a length greater than the length of the guidewire port *(see, for example, reference numerals 44 and 58 shown in Figures 6 and 8)*.

Dependent claim 25 recites the single lumen microcatheter of claim 13 wherein the guidewire port is defined by a perimeter wall having sides that tapers inward such that the perimeter of a top edge of the guidewire port is greater than the perimeter of a bottom edge of the guidewire port *(see, for example, Specification page 8, lines 15 – 18; reference numeral 48 shown in Figure 8)*.

Dependent claim 26 recites single lumen microcatheter of claim 25 wherein the sides are angled at approximately a 45-degree angle *(see, for example, Specification page 8, lines 17 – 18; reference numeral 48 shown in Figure 8)*.

Independent claim 27 recites a microcatheter *(see, for example, Specification page 5, lines 3 – 13; page 12, lines 1 -5; reference numeral 10 shown in Figure 1; reference numeral 75 shown in Figure 8)*, comprising:

an elongate shaft *(see, for example, Specification page 5, lines 14 – 16; page 5, line 21 – page 6 line 6; page 8, line 3 and lines 20 – 21; reference numeral 12 shown in Figures 1 and 2; reference numeral 32 shown in Figure 3; reference numeral 42 shown in Figures 4, 5, and 6)* having a distal end *(see, for example, Specification page 5, lines 14 – 15; reference numeral 16 shown in Figure 1)*and a proximal end*(see, for example, Specification page 5, lines 14 – 15;*

reference numeral 14 shown in Figure 1), the elongate shaft having an annular wall defining an outer surface and an inner surface of the elongate shaft, the inner surface defining a lumen extending through the elongate shaft fluidly connected to an opening at the distal end of the elongate shaft*(see, for example, Specification page 5, lines 14 – 15; reference numeral 14 shown in Figure 1)*; an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending through the annular wall of the elongate shaft from the inner surface of the elongate shaft to the outer surface of the elongate shaft*(see, for example, Specification page 8, lines 3 – 19; reference numeral 44 shown in Figures 4, 5, 6, 7, and 8)*; and a polymer sheath disposed over the elongate guidewire port*(see, for example, Specification page 8, line 20 – page 9, line 16; reference numeral 50 shown in Figures 6, 7, and 8)*, the polymer sheath having a wall defining an inner surface *(see, for example, Specification page 10, lines 10 – 11; reference numeral 62 shown in Figure 7)* and an outer surface of the polymer sheath *(see, for example, Specification page 10, lines 10 – 11; reference numeral 60 shown in Figure 7)*, the wall having a thickness measured from the inner surface to the outer surface of the polymer sheath, the polymer sheath including a passage *(see, for example, Specification page 9, line 14 – page 10, line 4; reference numeral 56 shown in Figures 6 and 7)* comprising an angled slit *(see, for example, Specification page 10, line 3 – page 11, line 4; reference numeral 58 shown in Figures 6 and 8)* extending radially through the wall of the polymer sheath from the outer surface to the inner surface of the polymer sheath, the angled slit extending at an angle such that the slit has a depth measured from the inner surface to the outer surface of the polymer sheath that is greater than the thickness of the wall of the polymer sheath *(see, for example, Specification page 10, lines 15 – 22; reference numerals D3 and D4 shown in Figure 7)*, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit being defined between a first edge of the polymer sheath and a second edge of the polymer sheath facing the first edge, each of the first edge and the second edge extending from the outer surface to the inner surface of the polymer sheath, wherein the first edge and the second edge are in contact with each other when no guidewire is extended through the passage *(see, for example, Specification page 10, line 20 – page 11, line 1)*, the passage in communication with the elongate guidewire port*(see, for example, Specification page 9, lines 14 -16)*, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining

substantially fluid tight in use when no guidewire is provided through the passage *(see, for example, Specification page 9, line 16 – page 10, line 2).*

Dependent claim 28 recites the microcatheter of claim 27 wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath *(see, for example, Specification page 10, lines 15 – 19).*

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

1. Whether claims 13, 15-17, and 21-28 are unpatentable under 35 U.S.C. § 103(a) over Pfenninger (U.S. Patent No. 5,306,247) in view of Allman et al. (U.S. Patent No. 6,346,093).

VII. ARGUMENT

Claims 13, 15-17, and 21-27 are patentable over Pfenninger (U.S. Patent No. 5,306,247) in view of Allman et al. (U.S. Patent No. 6,346,093) under 35 U.S.C. § 103(a).

A. Claims 13, 16, 21 – 23, and 25 – 26

Claim 13 recites:

13. A single lumen microcatheter, comprising:

an elongate shaft having a distal end and a proximal end, the elongate shaft having an outer surface and an inner surface, the inner surface defining a single lumen extending from the proximal end to the distal end of the elongate shaft and fluidly connecting the proximal end to an opening at the distal end of the elongate shaft;

an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and

a polymer sheath disposed over the elongate guidewire port, the polymer sheath having an inner surface and an outer surface, the polymer sheath having a length measured from a proximal end of the polymer sheath to a distal end of the polymer sheath, the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit having a length measured parallel to the length of the polymer sheath and parallel to the longitudinal axis of the elongate shaft, the length of the slit being less than the length of the polymer sheath such that the slit extends along only a portion of the length of the polymer sheath, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access

> through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage; and
>
> wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft.

Neither Pfenninger nor Allman et al., taken alone or in combination, appear to teach or suggest the microcatheter structure recited in independent claim 13. For example, neither Pfenninger nor Allman et al. appear to teach or suggest "the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft" among other limitations.

In formulating the rejection, Pfenninger is relied on as disclosing many of the presently claimed limitations. For example, page 6 of the Final Office Action mailed October 13, 2010 states, "Pfenninger discloses the claimed invention except for the longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided." Appellant respectfully asserts Pfenninger does not appear to teach or suggest many of the structural limitations recited in independent claim 13. For example, Pfenninger does not appear to teach or suggest a polymer sheath disposed over an elongate guidewire port or a polymer sheath including a passage comprising an angled slit. Pfenninger appears to disclose a balloon catheter (1) including an inflation lumen (6) and a guidewire lumen (7). The catheter shaft (2) appears to be formed from two separate catheter shafts (a proximal portion (18) and a distal portion (19)) bonded together at a connection point (17). The proximal portion (18) of the catheter shaft (2) appears to include a guidewire lumen (7) and an inflation lumen (6) disposed coaxially around the guidewire lumen (7). The distal portion (19) of the catheter shaft (2) appears to include a guidewire lumen (7) and an inflation lumen (6) arranged side-by-side, or biaxially. As illustrated in Figure 3 of Pfenninger, the coaxial proximal portion (18) appears to be attached to the distal biaxial portion (19) at a connection point (17). Pfenninger appears to disclose the tubular member (27) forming the inflation lumen (6) of the proximal portion (18) is disposed over the outer surface (20) of distal biaxial portion (19). The guidewire lumen (7) of the proximal portion (18) appears to be disposed within the guidewire lumen (7) of the distal portion (19) such that a continuous

guidewire lumen (7) is formed. Regarding the connection of the proximal portion (18) and the distal portion (19), Pfenninger discloses at column 7, lines 3 – 12:

> The inside tube 26 of the coaxial proximal shaft area 18 is inserted into the guide wire lumen 7 of the biaxial distal shaft area 19. Thus, the guide wire lumen 7 extends without interruption from the outermost proximal end of catheter 1 to the outermost distal end of the catheter. The outer tubing 27 is pushed over the shaft sheathing 20 of the biaxial distal shaft area 19. The two shaft areas are then joined together through the use of a binder or by welding.

Pfenninger further appears to disclose the catheter shaft (2) may include an opening (9) disposed in the side of the catheter shaft (2) for receiving the guidewire (8) into the guidewire lumen (7) at a location distal of the proximal end. As can be seen in Figure 4 of Pfenninger, the opening (9) appears to be a relatively large hole in the catheter shaft (2). Pfenninger appears to disclose the opening (9) is formed at the distal end of the proximal portion (18) of the catheter shaft (2). The opening (9) appears to be disposed through the wall (26) of the guidewire lumen (7) as well as the wall (27) of the proximal portion of the inflation lumen (6). With respect to the outlet opening (9), Pfenninger discloses at column 7, lines 40 – 45, "This cutout shape may be so large and so long that guide wire 8 easily comes out of shaft 1 when threaded into the catheter without requiring devices such as a ramp, etc., in lumen 7 to facilitate the catheter coming out of the shaft."

Nowhere does Pfenninger appear to teach or suggest a polymer sheath, or any other structure, is disposed over an elongate guidewire port as currently claimed. In formulating the rejection, the Examiner appears to be equating the outer tubular member (27) of the proximal portion (18) of the catheter shaft (2) of Pfenninger with the presently claimed polymer sheath. the Examiner asserts on page 4 of the Final Office Action mailed October 13, 2010, "Further note the Sheath (27), angled slit see figure below, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below)." As can be seen in Figures 3 and 4 of Pfenninger, the outer tubing (27) of the proximal portion (18) appears to form at least a portion of the outlet opening (9). Appellant respectfully asserts the outer tubing (27) cannot be considered as being disposed over an opening that is formed within said tubing as the Examiner appears to be asserting. Thus, Pfenninger cannot be considered as teaching or suggesting "a polymer sheath disposed over the elongate guidewire port" as currently claimed.

Further, in formulating the rejection, the Examiner appears to be asserting a sidewall of the opening formed within the outer tubular member of Pfenninger is equivalent to the presently claimed angled slit. For example, page 4 of the Final Office Action mailed October 13, 2010 asserts with reference to Pfenninger, "[f]urther note the Sheath (27), *angled slit* see figure below, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below)." Emphasis added. Appellant respectfully disagrees. In order to facilitate discussion, the annotated figure (Figure 3 of Pfenninger) included by the Examiner in the Final Office Action has been reproduced below.

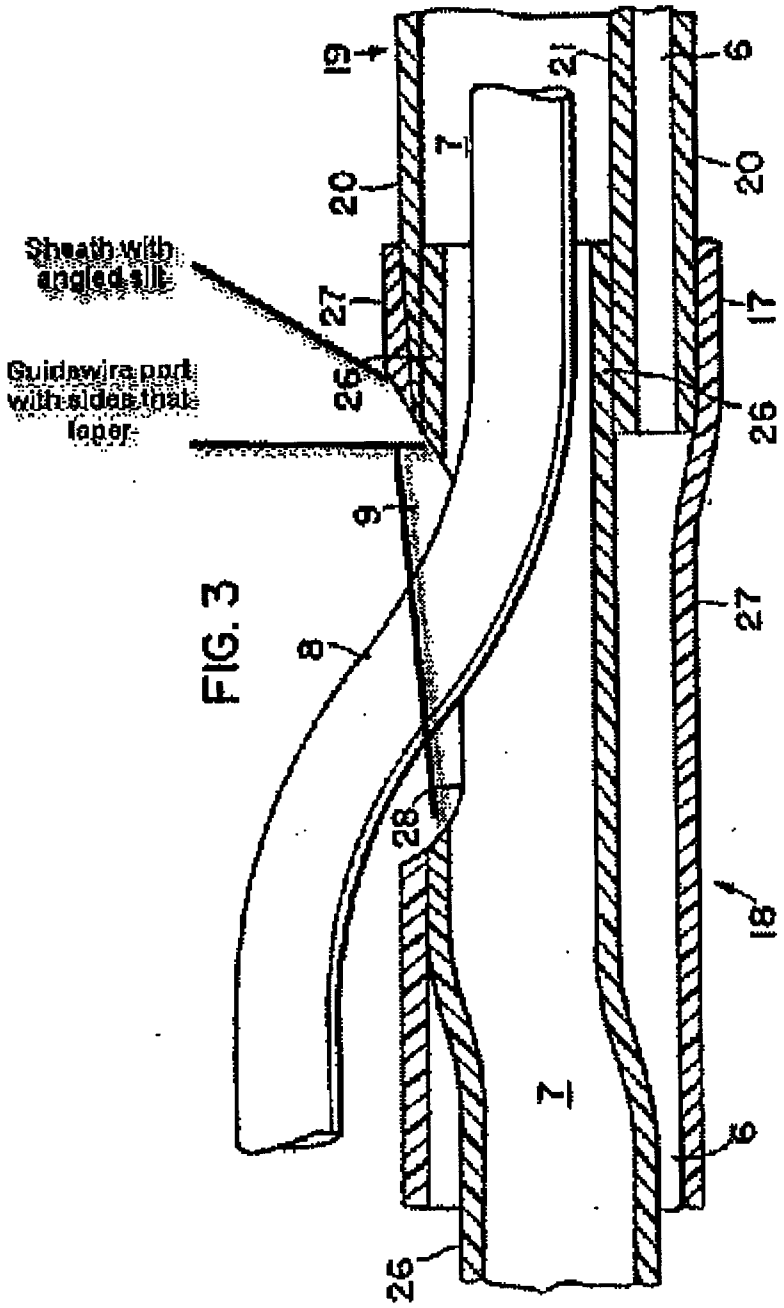

FIG. 3

As can be seen in the annotated Figure above, the Examiner appears to be asserting that the tapered sidewall forming the outlet opening is equivalent to the presently claimed angled slit.

MPEP 2111.01 states:

> during examination the USPTO must give claims their broadest reasonable interpretation >in light of the specification<.). This means that the words of the claim must be given their plain meaning unless **>the plain meaning is

> inconsistent with< the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004)

As one of ordinary skill in the art may be well aware, a slit is commonly used to define a narrow cut or opening. For example, Merriam-Webster defines slit as "a long narrow cut or opening" (http://www.merriam-webster.com/dictionary/slit, accessed July 2, 2010). The intended meaning of the word slit is further evidenced by the description as well as the figures (see, for example, reference numeral 58 shown in Figure 7). Furthermore, the Examiner appears to assert that because the side wall of the outlet of Pfenninger is angled, Pfenninger discloses an angled slit. Clearly, an angled wall cannot be equated to the presently claimed slit. Furthermore, independent claim 13 recites in part, "the slit having a length measured parallel to the length of the polymer sheath and parallel to the longitudinal axis of the elongate shaft." Even if one were to considered the angled wall of Pfenninger to be a "slit", a point not conceded, the angled wall of Pfenninger does not appear have a length extending parallel to a longitudinal axis of the elongate shaft.

Moreover, Allman et al. do not appear to teach or suggest the elements that are lacking in Pfenninger. For example, Allman et al. do not appear to teach or suggest a polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, as currently claimed. In formulating the rejection, the Examiner asserts:

> Allman teaches that it is known to use a longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided as set forth in paragraphs at column 8 lines 1-46 also see slit 118 in figure 4 and 4b or near 134 in figure 4c to provide and allow a guidewire to be radially slid into or out of the sheath assembly.

Appellant respectfully asserts Allman et al. do not appear to teach or suggest an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath. Allman et al. appear to disclose an endoscope exchange sheath (110) including a hub assembly (112) and a sheath (114). Allman et al. further appear to disclose that in some embodiments, the sheath (114) may include a slit (118) extending along the length thereof. The slit (118) appears to allow radial guidewire movement into and

about of the sheath assembly (110). The Examiner references Figures 4B and 4C of Allman et al. as allegedly illustrating an angled slit. Appellant respectfully disagrees. The slit, as illustrated by Allman et al. appears to be at 90 degrees. Allman et al. do not appear to teach or suggest otherwise.

Furthermore, neither Pfenninger nor Allman et al. appear to teach or suggest "the length of the slit being less than the length of the polymer sheath such that the slit extends along only a portion of the length of the polymer sheath" as currently claimed. As discussed above, Pfenninger does not appear to teach a polymer sheath or a slit within a polymer sheath. Thus, Pfenninger cannot be considered as disclosing a slit that extends along only a portion of the length of the polymer sheath. Allman et al. do not appear to remedy the noted shortcomings of Pfenninger. As discussed above, Allman et al. appear to disclose the slit (118) extends along the entire length of the sheath.

In formulating the rejection, the Examiner further asserts, "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly." Appellant respectfully disagrees. Pfenninger appears to disclose a balloon catheter system including a radial opening for allowing a guidewire to pass into a guidewire lumen. Thus, it appears Pfenninger already discloses a system in which a guidewire can be inserted and withdrawn through a radial opening in the catheter. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) states, "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". Emphasis added; see page 14 of the April 30, 2007 Decision. The Court further stated, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." See page 14 of the April 30, 2007 Decision.

Further, Pfenninger appears to teach the size and location of the opening has particular advantages. For example, Pfenninger discloses at column 4, lines 4 – 8, "[t]he arrangement of the outlet opening at the connection assures that the guide wire is always guided outside the guide catheter in the guide wire lumen and inside the catheter beyond the outlet opening in the

guide catheter." Pfenninger further discloses at column 7, lines 40 – 45, "[t]his cutout shape may be so large and so long that guide wire 8 easily comes out of shaft 1 when threaded into the catheter without requiring devices such as a ramp, etc., in lumen 7 to facilitate the catheter coming out of the shaft." Appellant respectfully asserts that the proposed modification, namely to include a sheath having a longitudinal slit disposed over the opening of Pfenninger, would change the principle operation of the device of Pfenninger. For example, it appears the sheath and slit would alter the function of the opening (9) of Pfenninger. MPEP 2143.01 VI states, "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)".

Therefore, for at least these reasons, neither Pfenninger nor Allman et al., taken alone or in combination appear to teach or suggest the microcatheter as currently claimed. Thus, even if one were to combine Pfenninger and Allman et al., one would not arrive at the device as claimed. Furthermore, there appears to be no motivation, suggestion or other reason for one of ordinary skill in the art to modify Pfenninger or Allman et al. to arrive at the device as claimed. The rejection is thus an error. Reversal of the rejection is respectfully requested. Appellant submits that claims 16, 21, 22, 23, 24, 25, and 26 are also believed to be patentable over Pfenninger and Allman as they depend from claim 13 and add significant limitations to further distinguish them from the cited art.

B. Claim 15

Claim 15 recites:

> 15. The single lumen microcatheter of claim 13, wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath.

Neither Pfenninger nor Allman et al., taken alone or in combination appear to teach or suggest an angled slit extending radially through a polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath. In formulating the rejection, the Examiner appears to rely on Allman et al. as disclosing such an angled slit. The Examiner asserts Allman et al. disclose such a slit in column 8, lines 1-46 and Figures 4, 4B and 4C.

Appellant respectfully disagrees. Allman et al. disclose at column 8, lines 2-6, "[s]heath assembly 110 includes a two-piece hub assembly 112 and a sheath 114 defining lumen 116 and having slit 118 extending longitudinally over its length, terminating at distal end 120." Allman et al. do not appear to disclose or suggest the orientation of the slit (118) relative to the outer surface of the sheath (114). Furthermore, as can be seen in Figure 4B of Allman et al., the slit (118) appears to be at 90 degrees to the outer surface of the polymer sheath (114). Allman et al. do not appear to teach or suggest the slit is at any angle other than 90 degrees as shown in Figure 4B. The only motivation for such an interpretation appears to be gleaned from the present application, which is improper. MPEP 2142 states, "However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." For at least these reasons, claim 15, which depends from claim 13, is believed to be clearly patentable over Pfenninger in view of Allman et al. Reversal of the rejection is respectfully requested.

C. Claim 17

Claim 17 recites:

> 17. The single lumen microcatheter of claim 13, wherein the angled slit is configured to accept both a guidewire and a sheath wherein the sheath is configured to accept the guidewire therein.

Neither Pfenninger nor Allman et al., taken alone or in combination, appear to teach or suggest an angled slit configured to accept both a guidewire and a sheath. The Examiner does not appear to address dependent claim 17 in the Final Office Action mailed October 13, 2010. As discussed above, Pfenninger appears to disclose a balloon catheter (1) including an inflation lumen (6) and a guidewire lumen (7). The catheter shaft (2) appears to be formed from two separate catheter shafts (a proximal portion (18) and a distal portion (19)) bonded together at a connection point (17). Pfenninger further appears to disclose the catheter shaft (2) may include an opening (9) disposed in the side of the catheter shaft (2) for receiving the guidewire (8) into the guidewire lumen (7) at a location distal of the proximal end. However, nowhere does Pfenninger appear to teach or suggest a sheath configured to accept a guidewire therein nor does Pfenninger appear to teach or suggest an angled slit configured to accept both a guidewire and a sheath. Allman et al. do not appear to teach or suggest that which Allman et al. lack. Allman et al. appear to disclose

a sheath assembly (110) including a hub assembly (112) and a sheath (114). The sheath (114) appears to include a longitudinal slit (118) extending along the length thereof. Allman et al. appear to disclose the slit allows for radial movement of a guidewire into and out of the sheath (114). However, nowhere do Allman et al. appear to teach or suggest a sheath configured to accept a guidewire therein nor do Allman et al. appear to teach or suggest an angled slit configured to accept both a guidewire and a sheath. For at least these reasons, claim 17, which depends from claim 13, is believed to be clearly patentable over Pfenninger in view of Allman et al. Reversal of the rejection is respectfully requested.

D. Claim 27

Claim 27 recites:

> 27. A microcatheter, comprising:
> an elongate shaft having a distal end and a proximal end, the elongate shaft having an annular wall defining an outer surface and an inner surface of the elongate shaft, the inner surface defining a lumen extending through the elongate shaft fluidly connected to an opening at the distal end of the elongate shaft;
> an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending through the annular wall of the elongate shaft from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and
> a polymer sheath disposed over the elongate guidewire port, the polymer sheath having a wall defining an inner surface and an outer surface of the polymer sheath, the wall having a thickness measured from the inner surface to the outer surface of the polymer sheath, the polymer sheath including a passage comprising an angled slit extending radially through the wall of the polymer sheath from the outer surface to the inner surface of the polymer sheath, the angled slit extending at an angle such that the slit has a depth measured from the inner surface to the outer surface of the polymer sheath that is greater than the thickness of the wall of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit being defined between a first edge of the polymer sheath and a second edge of the polymer sheath facing the first edge, each of the first edge and the second edge extending from the outer surface to the inner surface of the polymer sheath, wherein the first edge and the second edge are in contact with each other when no guidewire is extended through the passage, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage.

Neither Pfenninger nor Allman et al., taken alone or in combination, appear to teach or suggest the microcatheter structure recited in independent claim 27. For example, neither Pfenninger nor

Allman et al. appear to teach or suggest "the polymer sheath including a passage comprising an angled slit extending radially through the wall of the polymer sheath from the outer surface to the inner surface of the polymer sheath, the angled slit extending at an angle such that the slit has a depth measured from the inner surface to the outer surface of the polymer sheath that is greater than the thickness of the wall of the polymer sheath" among other limitations.

In formulating the rejection, Pfenninger is relied on as disclosing many of the presently claimed limitations. For example, page 6 of the Final Office Action mailed October 13, 2010 states, "Pfenninger discloses the claimed invention except for the longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided." Appellant respectfully asserts Pfenninger does not appear to teach or suggest many of the structural limitations recited in independent claim 27. For example, Pfenninger does not appear to teach or suggest a polymer sheath disposed over an elongate guidewire port or a polymer sheath including a passage comprising an angled slit. Pfenninger appears to disclose a balloon catheter (1) including an inflation lumen (6) and a guidewire lumen (7). The catheter shaft (2) appears to be formed from two separate catheter shafts (a proximal portion (18) and a distal portion (19)) bonded together at a connection point (17). The proximal portion (18) of the catheter shaft (2) appears to include a guidewire lumen (7) and an inflation lumen (6) disposed coaxially around the guidewire lumen (7). The distal portion (19) of the catheter shaft (2) appears to include a guidewire lumen (7) and an inflation lumen (6) arranged side-by-side, or biaxially. As illustrated in Figure 3 of Pfenninger, the coaxial proximal portion (18) appears to be attached to the distal biaxial portion (19) at a connection point (17). Pfenninger appears to disclose the tubular member (27) forming the inflation lumen (6) of the proximal portion (18) is disposed over the outer surface (20) of distal biaxial portion (19). The guidewire lumen (7) of the proximal portion (18) appears to be disposed within the guidewire lumen (7) of the distal portion (19) such that a continuous guidewire lumen (7) is formed. Regarding the connection of the proximal portion (18) and the distal portion (19), Pfenninger discloses at column 7, lines 3 – 12:

> The inside tube 26 of the coaxial proximal shaft area 18 is inserted into the guide wire lumen 7 of the biaxial distal shaft area 19. Thus, the guide wire lumen 7 extends without interruption from the outermost proximal end of catheter 1 to the outermost distal end of the catheter. The outer tubing 27 is pushed over the shaft

> sheathing 20 of the biaxial distal shaft area 19. The two shaft areas are then joined together through the use of a binder or by welding.

Pfenninger further appears to disclose the catheter shaft (2) may include an opening (9) disposed in the side of the catheter shaft (2) for receiving the guidewire (8) into the guidewire lumen (7) at a location distal of the proximal end. As can be seen in Figure 4 of Pfenninger, the opening (9) appears to be a relatively large hole in the catheter shaft (2). Pfenninger appears to disclose the opening (9) is formed at the distal end of the proximal portion (18) of the catheter shaft (2). The opening (9) appears to be disposed through the wall (26) of the guidewire lumen (7) as well as the wall (27) of the proximal portion of the inflation lumen (6). With respect to the outlet opening (9), Pfenninger discloses at column 7, lines 40 – 45, "This cutout shape may be so large and so long that guide wire 8 easily comes out of shaft 1 when threaded into the catheter without requiring devices such as a ramp, etc., in lumen 7 to facilitate the catheter coming out of the shaft."

Nowhere does Pfenninger appear to teach or suggest a polymer sheath, or any other structure, is disposed over an elongate guidewire port as currently claimed. In formulating the rejection, the Examiner appears to be equating the outer tubular member (27) of the proximal portion (18) of the catheter shaft (2) of Pfenninger with the presently claimed polymer sheath. The Examiner asserts on page 4 of the Final Office Action mailed October 13, 2010, "Further note the Sheath (27), angled slit see figure below, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below)." As can be seen in Figures 3 and 4 of Pfenninger, the outer tubing (27) of the proximal portion (18) appears to form at least a portion of the outlet opening (9). Appellant respectfully asserts the outer tubing (27) cannot be considered as being disposed over an opening that is formed within said tubing as the Examiner appears to be asserting. Thus, Pfenninger cannot be considered as teaching or suggesting "a polymer sheath disposed over the elongate guidewire port" as currently claimed.

Further, in formulating the rejection, the Examiner appears to be asserting a sidewall of the opening formed within the outer tubular member of Pfenninger is equivalent to the presently claimed angled slit. For example, page 4 of the Final Office Action mailed October 13, 2010 asserts with reference to Pfenninger, "[f]urther note the Sheath (27), *angled slit* see figure below, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below)." Emphasis added. Appellant respectfully disagrees. In order to facilitate discussion, the annotated figure

(Figure 3 of Pfenninger) included by the Examiner in the Final Office Action has been reproduced above. As can be seen in the annotated Figure above, the Examiner appears to be asserting that the tapered sidewall forming the outlet opening is equivalent to the presently claimed angled slit. MPEP 2111.01 states:

> during examination the USPTO must give claims their broadest reasonable interpretation >in light of the specification<.). This means that the words of the claim must be given their plain meaning unless **>the plain meaning is inconsistent with< the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004)

As one of ordinary skill in the art may be well aware, a slit is commonly used to define a narrow cut or opening. For example, Merriam-Webster defines slit as "a long narrow cut or opening" (http://www.merriam-webster.com/dictionary/slit, accessed July 2, 2010). The intended meaning of the word slit is further evidenced by the description as well as the figures (see, for example, reference numeral 58 shown in Figure 7). Furthermore, the Examiner appears to assert that because the side wall of the outlet of Pfenninger is angled, Pfenninger discloses an angled slit. Clearly, an angled wall cannot be equated to the presently claimed slit. Furthermore, independent claim 27 recites in part, "the slit disposed parallel to a longitudinal axis of the elongate shaft." Even if one were to consider the angled wall of Pfenninger to be a "slit", a point not conceded, the angled wall of Pfenninger does not appear to extend parallel to a longitudinal axis of the elongate shaft as currently claimed.

Moreover, Allman et al. do not appear to teach or suggest the elements that are lacking in Pfenninger. For example, Allman et al. do not appear to teach or suggest a polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, as currently claimed. In formulating the rejection, the Examiner asserts:

> Allman teaches that it is known to use a longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided as set forth in paragraphs at column 8 lines 1-46 also see slit 118 in figure 4 and 4b or near 134 in figure 4c to provide and allow a guidewire to be radially slid into or out of the sheath assembly.

Appellant respectfully asserts Allman et al. do not appear to teach or suggest an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath. Allman et al. appear to disclose an endoscope exchange sheath (110) including a hub assembly (112) and a sheath (114). Allman et al. further appear to disclose that in some embodiments, the sheath (114) may include a slit (118) extending along the length thereof. The slit (118) appears to allow radial guidewire movement into and about of the sheath assembly (110). The Examiner references Figures 4B and 4C of Allman et al. as allegedly illustrating an angled slit. Appellant respectfully disagrees. The slit, as illustrated by Allman et al., appears to be at 90 degrees and thus have a depth equal to the thickness of the sheath. Allman et al. do not appear to teach or suggest otherwise.

In formulating the rejection, the Examiner further asserts, "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly." Appellant respectfully disagrees. Pfenninger appears to disclose a balloon catheter system including a radial opening for allowing a guidewire to pass into a guidewire lumen. Thus, it appears Pfenninger already discloses a system in which a guidewire can be inserted and withdrawn through a radial opening in the catheter. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) states, "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". Emphasis added; see page 14 of the April 30, 2007 Decision. The Court further stated, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." See page 14 of the April 30, 2007 Decision.

Further, Pfenninger appears to teach the size and location of the opening has particular advantages. For example, Pfenninger discloses at column 4, lines 4 – 8, "[t]he arrangement of the outlet opening at the connection assures that the guide wire is always guided outside the guide catheter in the guide wire lumen and inside the catheter beyond the outlet opening in the guide catheter." Pfenninger further discloses at column 7, lines 40 – 45, "[t]his cutout shape may be so large and so long that guide wire 8 easily comes out of shaft 1 when threaded into the

catheter without requiring devices such as a ramp, etc., in lumen 7 to facilitate the catheter coming out of the shaft." Appellant respectfully asserts that the proposed modification, namely to include a sheath having a longitudinal slit disposed over the opening of Pfenninger, would change the principle operation of the device of Pfenninger. For example, it appears the sheath and slit would alter the function of the opening (9) of Pfenninger. MPEP 2143.01 VI states, "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)".

Therefore, for at least these reasons, neither Pfenninger nor Allman et al., taken alone or in combination appear to teach or suggest the microcatheter as currently claimed. Thus, even if one were to combine Pfenninger and Allman et al., one would not arrive at the device as claimed. Furthermore, there appears to be no motivation, suggestion or other reason for one of ordinary skill in the art to modify Pfenninger or Allman et al. to arrive at the device as claimed. The rejection is thus an error. Reversal of the rejection is respectfully requested.

E. Claim 28

Claim 28 recites:

> 28. The microcatheter of claim 27, wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath.

Neither Pfenninger nor Allman et al., taken alone or in combination, appear to teach or suggest an angled slit extending radially through a polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath. In formulating the rejection, the Examiner appears to rely on Allman et al. as disclosing such an angled slit. The Examiner asserts Allman et al. disclose such a slit in column 8, lines 1-46 and Figures 4, 4B and 4C. Appellant respectfully disagrees. Allman et al. disclose at column 8, lines 2-6, "[s]heath assembly 110 includes a two-piece hub assembly 112 and a sheath 114 defining lumen 116 and having slit 118 extending longitudinally over its length, terminating at distal end 120." Allman et al. do not appear to disclose or suggest the orientation of the slit (118) relative to the outer surface of the sheath (114). Furthermore, as can be seen in Figure 4B of Allman et al., the slit (118) appears to

be at 90 degrees to the outer surface of the polymer sheath (114). Allman et al. do not appear to teach or suggest the slit is at any angle other than 90 degrees as shown in Figure 4B. The only motivation for such an interpretation appears to be gleaned from the present application, which is improper. MPEP 2142 states, "However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." For at least these reasons, claim 28, which depends from claim 27, is believed to be clearly patentable over Pfenninger in view of Allman et al. Reversal of the rejection is respectfully requested.

VIII. CONCLUSION

For the reasons stated above, the Examiner's rejection of claims 13, 15-17, and 21-28 under 35 U.S.C. § 103 should be reversed.

Respectfully submitted,

Sean McFerran

By his Attorney,

Date: May 9, 2011

J. Scot Wickhem, Reg. No. 41,376
SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

IX. CLAIMS APPENDIX

13. A single lumen microcatheter, comprising:

an elongate shaft having a distal end and a proximal end, the elongate shaft having an outer surface and an inner surface, the inner surface defining a single lumen extending from the proximal end to the distal end of the elongate shaft and fluidly connecting the proximal end to an opening at the distal end of the elongate shaft;

an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and

a polymer sheath disposed over the elongate guidewire port, the polymer sheath having an inner surface and an outer surface, the polymer sheath having a length measured from a proximal end of the polymer sheath to a distal end of the polymer sheath, the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit having a length measured parallel to the length of the polymer sheath and parallel to the longitudinal axis of the elongate shaft, the length of the slit being less than the length of the polymer sheath such that the slit extends along only a portion of the length of the polymer sheath, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage; and

wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft.

15. The single lumen microcatheter of claim 13, wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath.

16. The single lumen microcatheter of claim 13, wherein the angled slit extends from the outer surface of the polymer sheath to the inner surface of the polymer sheath.

17. The single lumen microcatheter of claim 13, wherein the angled slit is configured to accept both a guidewire and a sheath wherein the sheath is configured to accept the guidewire therein.

21. The single lumen microcatheter of claim 13 wherein the guidewire port has a length and a width, wherein the length is at least three times greater than the width.

22. The single lumen microcatheter of claim 21, wherein the length is at least six times greater than the width.

23. The single lumen microcatheter of claim 21, wherein the guidewire port has a first wall and a second wall, wherein the first wall and the second wall extend parallel to the longitudinal axis of the elongate shaft and wherein the guidewire port length also extends parallel to the longitudinal axis of the elongate shaft.

24. The single lumen microcatheter of claim 13, wherein the slit has a length greater than the length of the guidewire port.

25. The single lumen microcatheter of claim 13, wherein the guidewire port is defined by a perimeter wall having sides that tapers inward such that the perimeter of a top edge of the guidewire port is greater than the perimeter of a bottom edge of the guidewire port.

26. The single lumen microcatheter of claim 25, wherein the sides are angled at approximately a 45-degree angle.

27. A microcatheter, comprising:

an elongate shaft having a distal end and a proximal end, the elongate shaft having an annular wall defining an outer surface and an inner surface of the elongate shaft, the inner surface defining a lumen extending through the elongate shaft fluidly connected to an opening at the distal end of the elongate shaft;

an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending through the annular wall of the elongate shaft from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and

a polymer sheath disposed over the elongate guidewire port, the polymer sheath having a wall defining an inner surface and an outer surface of the polymer sheath, the wall having a thickness measured from the inner surface to the outer surface of the polymer sheath, the polymer sheath including a passage comprising an angled slit extending radially through the wall of the polymer sheath from the outer surface to the inner surface of the polymer sheath, the angled slit extending at an angle such that the slit has a depth measured from the inner surface to the outer surface of the polymer sheath that is greater than the thickness of the wall of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit being defined between a first edge of the polymer sheath and a second edge of the polymer sheath facing the first edge, each of the first edge and the second edge extending from the outer surface to the inner surface of the polymer sheath, wherein the first edge and the second edge are in contact with each other when no guidewire is extended through the passage, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage.

28. The microcatheter of claim 27, wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None